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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,021	02/18/2005	Mitsutaka Nakamura	0020-5041PUS2	3141

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
09/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/525,021	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,8,11,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5, 8, 11 and 20-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Receipt of Applicants arguments/Remarks and amended claims filed on 08/08/08 are acknowledged.

Claims 3-4, 6-7, 9-10 and 12-19 have been canceled and new claims 20-21 have been added in this application.

Accordingly, claims **1-2, 5, 8, 11 and 20-21** are being examined on the merits herein.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-2, 5, 8, 11 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommerville et al. (WO 03/066039 A1) in view of Wong et al. (US 6,964,962) and EP 464846 by Saji et al.

It is noted that (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl-methyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1] heptanedicarboximide hydrochloride is known in the art as SM-13496 (see page 7, lines 5-8 of the

specification). Thus, SM-13496 is the hydrochloride salt of (1R,2S,3R,4S)-N-[(1R,2R)-2-[4-(1,2-benzoisothiazol-3-yl)-1-piperazinyl-methyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide.

Sommerville et al. teach a method of treating schizophrenia comprising atypical antipsychotics, namely SM-13496 (abstract; and page 5, line 35). Sommerville et al. further teaches positive and negative symptoms are often increased during the acute phase, or the florid psychotic phase, of schizophrinia and that the method of Sommerville et al. is aimed at treatment during the acute phase of schizophrenia (page 4, lines 16-23).

Sommerville et al. do not explicitly teach the dose of SM-13496 (see page 7, lines 23-25).

Wong et al. teach 0.05 to 7500 mg/day/patient of SM-13496 can be used to schizophrenia (see column 4, lines 51-58; and Table in column 8, line 16), which details the daily dose of SM-13496 that can be given to the patient and thus may be a once a day administration. Moreover, Wong et al. teach 0.05 to 7500 mg/day/patient of SM-13496 can be used to schizophrenia (column 4, lines 51-58; and Table in column 8, line 16). While Wong et al. teach wide range of dosage, Saji et al. disclose specific ranges of dosage to treat schizophrenia.

Saji et al. teaches oral preparations of the claimed compound containing 10 mg, 20 mg, or 40 mg of a hydrochloride of formula I. Which are efficacious for treating schizophrenia (an integration dysfunction syndrome)(see page 13, lines 25-30).

It would have been obvious to one of ordinary skill in the art to optimize the dosage range of the claimed drug in order to obtain the most efficacious dosage range by doing experimental manipulations. Based on the teachings of Wong et al. and Saji et al. one would have been motivated to perform experimental manipulations with the dosage range in order to treat schizophrenia in a most efficacious dosage amount as taught by Sommerville et al. It is to be noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955) absent evidence to the contrary.

Response to Arguments

4. Applicant's arguments with respect to claims 1-2, 5, 8, 11 and 20-21 have been considered but are moot in view of the new ground(s) of rejection.

Response to 37 CFR 1.132 Declaration

5. The declaration and the study of maximum tolerated dose of SM-13496 is not sufficient to overcome the rejection based on the prior art since applicants have not shown comparative analysis of the prior art versus the claimed invention. Additionally, the reference by Saji et al. disclose the dosage range of the claimed compound which can be in the range of 10 mg, 20 mg and 40 mg, which overlap with the claimed dosage range of the claimed compound. Applicants have not shown any unexpected result with

respect to the claimed dosage range. Prior art by Wong et al. and Saji et al. teach the dosage range which overlap with the instant dosage range.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612
/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612